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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,213	11/14/2001	Brenda F. Baker	RTS-0327	1275

32650 7590 12/23/2004

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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/000,213	BAKER ET AL.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-9,11-15 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4-9, 11-15, and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicants Amendment and Remarks filed October 19, 2004.

Claims 1, 2, 4-9, 11-15, and 30 are pending in the instant application. Claim 30 has been amended.

Claims 1, 2, 4-9, 11-15, and 30 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

In the previous Office Action mailed July 20, 2004, claim 30 was objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. **This rejection is withdrawn** in view of Applicants amendment to the claim to rewrite the claims in independent form.

Claim Rejections - 35 USC § 102

In the previous Office Action mailed July 20, 2004, claims 1, 2, 4, 5, 6, 8, 9, 12, 13, 14, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Gimeno et al. [U.S. Patent No. 5,955,306]. **This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed July 20, 2004.

Response to Arguments

In response to this rejection, Applicants first argue that the Examiner has not provided a rationale or evidence tending to show inherency. Applicants contend that the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. Applicants further contend that "in relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Applicants rely on MPEP §2112.

Applicants secondly argue that the Examiner has not indicated why the evidence shows that an antisense oligonucleotide targeted to Tub protein, as shown in the Gimeno et al. reference, when taken among all oligonucleotides known at the time of fling of the instant application, would be sufficient to identify the compound of Applicants' claimed invention, e.g., an antisense nucleotide which specifically hybridizes within nucleotides 1710 to 1757 of a nucleic acid molecule encoding human vitamin D nuclear receptor (SEQ ID N0:3) and which inhibits the expression of human vitamin D nuclear receptor. Applicants contend that of the oligonucleotides known to hybridize to target regions at the time of filing of the instant application, no antisense oligonucleotides were known to specifically hybridize within the claimed region of Applicants' claimed invention

Applicant's arguments have been fully considered, but are not found persuasive. Regarding Applicants first argument, the Examiner believes that she has provided a rationale or evidence tending to show inherency. For example, see the previous Office Action mailed July 20, 2004 at page 7, where the Examiner discussed that, "the antisense oligonucleotide targeted to

Tub Interactor disclosed by Gimeno et al. exhibits almost 89% local similarity to nucleobases 1714-1731 of SEQ ID NO:3 of the instant invention". The Examiner goes on to discuss that, "given this high degree of similarity, the antisense oligonucleotide targeted to Tub Interactor disclosed by Gimeno et al. **meets the structural limitations** of the claimed invention and would be expected to "specifically hybridize" since the instant specification at page 10, lines 9-12 teaches, "it is understood in the art that the sequence of an antisense compound need not be 100% complementary to that of its target nucleic acid to be specifically hybridizable." Since the prior art antisense oligonucleotide meets the only structure requirement in the claim, it would be expected to "specifically hybridize" to bases 1714-1731 of SEQ ID NO:3, absent evidence to the contrary. It is noted that simply because the prior art does not say the antisense oligonucleotide disclosed by Gimeno et al. inhibits expression of vitamin D nuclear receptor, is not evidence it would not. It falls to applicant to show data or provide some line of sound scientific reasoning why the prior art antisense oligonucleotide, which would "specifically hybridize" to bases 1714-1731 of SEQ ID NO:3 based on structure, would also not possess the property to inhibit the gene it specifically hybridizes with, since per the claim, this is the only claimed structural requirement the oligonucleotide need have.

Regarding Applicants second argument, Applicant is pointed to the previous Office Action mailed July 20, 2004 at pages 7 and 8, and reminded of MPEP 2112.01, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of

the applicant and the prior art are the same, **the applicant has the burden of showing that they are not**." The PTO does not have the ability to test whether the antisense oligonucleotide targeted to Tub Interactor disclosed by Gimeno et al. will specifically hybridize within nucleotides 1710 to 1757 of a nucleic acid molecule encoding human vitamin D nuclear receptor (SEQ ID NO:3) as claimed. However, because the antisense oligonucleotide targeted to Tub Interactor disclosed by Gimeno et al. exhibits almost 89% local similarity to nucleobases 1714-1731 of SEQ ID NO:3, and meets the structural limitations of the claimed invention, it would be expected to "specifically hybridize", given Applicants broad definition in the specification at page 10, absent evidence to the contrary.

Therefore, given these discussions, the Examiner has clearly provided a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.

In the previous Office Action mailed July 20, 2004, claims 1, 2, 4-9, 11-15, and 30 were rejected under 35 U.S.C. 102(b) as being anticipated by Cowsert et al. [U.S. Patent No. 6,566,131]. It is noted that the Examiner has made an inadvertent error, as this rejection should have been a 102(e) rejection, not a 102(b) rejection, given the issue date of the patent and Applicants' filing date for the instant application. The Examiner would like to apologize for this inadvertent error and thank Applicants for pointing out this inadvertent error in their response filed October 19, 2004. Therefore, claims 1, 2, 4-9, 11-15, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Cowsert et al. [U.S. Patent No. 6,566,131]. **This rejection is**

maintained for the reasons of record set forth in the previous Office Action mailed July 20, 2004.

Response to Arguments

In response to this rejection, Applicants first argue that the Examiner has not provided a rationale or evidence tending to show inherency. Applicants contend that the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. Applicants further contend that "in relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Applicants rely on MPEP §2112.

Applicants secondly argue that despite the Examiner's assertions, the antisense oligonucletoide disclosed by Cowsert et al. was not effective *in vitro* as it provided no inhibition of human Smad6 (see Table 1). Applicants contend that since the antisense oligonucletoide disclosed by Cowsert et al. was not effective *in vitro* against Smad6, it is novel in view of Cowsert et al.

Applicant's arguments have been fully considered, but are not found persuasive. Regarding Applicants first argument, the Examiner believes that she has provided a rationale or evidence tending to show inherency. For example, see the previous Office Action mailed July 20, 2004 at page 5, where the Examiner discussed that, "the antisense oligonucleotide targeted to Smad6 disclosed by Cowsert et al. exhibits almost 94% local similarity to nucleobases 1723-1738 of SEQ ID NO:3 of the instant invention". The Examiner goes on to discuss that, "given

this high degree of similarity, the antisense oligonucleotide targeted to Smad6 disclosed by Cowsert et al. meets the structural limitations of the claimed invention and would be expected to "specifically hybridize" since the instant specification at page 10, lines 9-12 teaches, "it is understood in the art that the sequence of an antisense compound need not be 100% complementary to that of its target nucleic acid to be specifically hybridizable." Since the prior art antisense oligonucleotide meets the only structure requirement in the claim, it would be expected to "specifically hybridize" to bases 1723-1738 of SEQ ID NO:3, absent evidence to the contrary. It is noted that simply because the prior art does not say the antisense oligonucleotide disclosed by Cowsert et al. inhibits expression of vitamin D nuclear receptor, is not evidence it would not. It falls to applicant to show data or provide some line of sound scientific reasoning why the prior art antisense oligonucleotide, which would "specifically hybridize" to bases 1723-1738 of SEQ ID NO:3 based on structure, would also not possess the property to inhibit the gene it specifically hybridizes with, since per the claim, this is the only claimed structural requirement the oligonucleotide need have.

Regarding Applicants second argument, Applicant is pointed to the previous Office Action mailed July 20, 2004 at pages 5 and 6, and reminded of MPEP 2112.01, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, **the applicant has the burden of showing that they are not**." The PTO does not have the ability to test whether the antisense oligonucleotide

targeted to Smad6 disclosed by Cowsert et al. will specifically hybridize within nucleotides 1723 to 1738 of a nucleic acid molecule encoding human vitamin D nuclear receptor (SEQ ID NO:3) as claimed. However, because the antisense oligonucleotide targeted to Smad6 disclosed by Cowsert et al. exhibits almost 94% local similarity to nucleobases 1723-1738 of SEQ ID NO:3, and meets the structural limitations of the claimed invention, it would be expected to "specifically hybridize", given Applicants broad definition in the specification at page 10, absent evidence to the contrary.

Therefore, given these discussions, the Examiner has clearly provided a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (571) 272-0758. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tcg
December 16, 2004